

We Claim:

- 1 1. An extended release pharmaceutical composition comprising:
 - 2 a blend of phenytoin sodium; and
 - 3 one or more hydrophilic polymers; wherein the blend forms a matrix after
 - 4 contacting an aqueous media and the matrix retains at least about 20% of the
 - 5 phenytoin after 1 hour.
- 1 2. The composition according to claim 1, wherein the matrix retains at least about
- 2 30% of the phenytoin after 1 hour.
- 1 3. The composition according to claim 1, wherein the matrix retains at least about
- 2 60% of the phenytoin after 1 hour.
- 1 4. The composition according to claim 1, wherein the pharmaceutical
- 2 composition comprises a capsule containing the blend.
- 1 5. The composition according to claim 4, wherein the blend comprises a powder.
- 1 6. The composition according to claim 1, wherein the composition comprises
- 2 from about 40 percent to about 70 percent by weight of phenytoin sodium.
- 1 7. The composition according to claim 1, wherein the composition comprises
- 2 from about 10 percent to about 30 percent by weight of the one or more
- 3 hydrophilic polymers.
- 1 8. The composition according to claim 7, wherein the one or more hydrophilic
- 2 polymers comprise one or more of carbohydrate gum, cellulose ether, acrylic
- 3 acid polymer, and mixtures thereof.
- 1 9. The composition according to claim 8, wherein the carbohydrate gum
- 2 comprises one or more of xanthan gum, tragacanth gum, gum karaya, guar
- 3 gum, acacia, gellan gum, locust bean gum, and mixtures thereof.
- 1 10. The composition according to claim 9, wherein the carbohydrate gum
- 2 comprises xanthan gum.
- 1 11. The composition according to claim 10, wherein the cellulose ether comprises
- 2 one or more of methyl cellulose, hydroxypropyl cellulose, hydroxypropyl
- 3 methyl cellulose, hydroxyethyl cellulose, hydroxypropyl butyl cellulose,
- 4 carboxymethyl cellulose, and combinations thereof.

- 1 33. The process according to claim 27, wherein the one or more hydrophilic
2 polymers are selected from one or more of carbohydrate gum, cellulose ether,
3 acrylic acid polymer, and mixtures thereof.
- 1 34. The process according to claim 33, wherein the carbohydrate gum comprises
2 one or more of xanthan gum, tragacanth gum, gum karaya, guar gum, acacia,
3 gellan gum, locust bean gum, and mixtures thereof.
- 1 35. The process according to claim 34, wherein the carbohydrate gum comprises
2 xanthan gum.
- 1 36. The process according to claim 34, wherein the cellulose ether comprises one
2 or more of methyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl
3 cellulose, hydroxyethyl cellulose, hydroxypropyl butyl cellulose,
4 carboxymethyl cellulose, and combinations thereof.
- 1 37. The process according to claim 36, wherein the cellulose ether comprises
2 hydroxypropyl cellulose.
- 1 38. The process according to claim 36, wherein the cellulose ether comprises
2 hydroxypropyl methylcellulose.
- 1 39. The process according to claim 33, wherein the acrylic acid polymer comprises
2 carboxy vinyl polymer.
- 1 40. The process according to claim 33, wherein the one or more hydrophilic
2 polymers comprise a combination of a cellulose ether and carbohydrate gum.
- 1 41. The process according to claim 40, wherein the cellulose ether comprises a
2 combination of hydroxypropyl cellulose and hydroxypropyl methylcellulose
3 and the carbohydrate gum comprises xanthan gum.
- 1 42. The process according to claim 27, further comprising blending one or more
2 pharmaceutically acceptable excipients with the phenytoin sodium and one or
3 more hydrophilic polymers.
- 1 43. The process according to claim 42, wherein the pharmaceutically acceptable
2 excipients comprise one or more of diluents, lubricants, and glidants.

- 1 44. The process according to claim 27, wherein the composition has the following
2 in vitro dissolution profile when tested using USP Apparatus I in water at 75
3 rpm:
4 a) not more than about 35 percent released in about 30 minutes,
5 b) between about 30 and about 75 percent released in about 60
6 minutes
7 c) not less than about 65 percent released in about 120 minutes.
- 1 45. A method for controlling or treating one or more of generalized tonic-clonic
2 (grand mal) seizures and complex partial (psychomotor, temporal lobe)
3 seizures and prevention and treatment of seizures occurring during or following
4 neurosurgery in a patient in need thereof, the method comprising administering
5 an extended-release pharmaceutical composition comprising:
6 a blend of phenytoin sodium; and
7 one or more hydrophilic polymers; wherein the blend forms a matrix after
8 contacting an aqueous media and the matrix retains at least about 20% of the
9 phenytoin after 1 hour.
- 1 46. The method according to claim 45, further comprising administering an
2 additional pharmaceutically active agent.
- 1 47. The method according to claim 46, wherein the additional pharmaceutically
2 active agent comprises one or both of phenobarbitone and pentobarbital.
- 1 48. The method according to claim 45, wherein the one or more hydrophilic
2 polymers comprise one or more of carbohydrate gum, cellulose ether, acrylic
3 acid polymer, and mixtures thereof.